

## PATENT COOPERATION TREATY

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NOTIFICATION CONCERNING  
 TRANSMITTAL OF COPY OF INTERNATIONAL  
 PRELIMINARY REPORT ON PATENTABILITY  
 (CHAPTER I OF THE PATENT COOPERATION  
 TREATY)  
 (PCT Rule 44bis.1(c))

From the INTERNATIONAL BUREAU

To:

**Docket System**  
**Status Report**  
**Docket Book**  
 ✓  
 ✓  
 ✓  
*JPRP*

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 Marlton, NJ 08053  
 ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 04 August 2005 (04.08.2005)
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Applicant's or agent's file reference DC-0248
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International application No. PCT/US2004/001382
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International filing date (day/month/year) 20 January 2004 (20.01.2004)
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**IMPORTANT NOTICE**

Priority date (day/month/year) 21 January 2003 (21.01.2003)
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Applicant TRUSTEES OF DARTMOUTH COLLEGE et al
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The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland
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Authorized officer
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Simin Baharlou
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## PATENT COOPERATION TREATY

**PCT****INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference DC-0248	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/US2004/001382	International filing date ( <i>day/month/year</i> ) 20 January 2004 (20.01.2004)	Priority date ( <i>day/month/year</i> ) 21 January 2003 (21.01.2003)	
International Patent Classification (IPC) or national classification and IPC <sup>7</sup> A61K 31/519, C07D 487/02, C12Q 1/02			
Applicant TRUSTEES OF DARTMOUTH COLLEGE			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report   |
| <input type="checkbox"/> Box No. II           | Priority  |
| <input type="checkbox"/> Box No. III          | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/> Box No. IV           | Lack of unity of invention  |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI           | Certain documents cited   |
| <input type="checkbox"/> Box No. VII          | Certain defects in the international application  |
| <input type="checkbox"/> Box No. VIII         | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

Date of issuance of this report 22 July 2005 (22.07.2005)
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The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer  Simin Baharlou
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**PATENT COOPERATION TREATY**

From the  
**INTERNATIONAL SEARCHING AUTHORITY**

REC'D 18 FEB 2005

**PCT** WIPO PCT

To:  
JANE MASSEY LICATA  
LICATA & TYRRELL PC  
66 E. MAIN STREET  
MARLTON, NJ 08053

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

		Date of mailing (day/month/year)
		<b>FOR FURTHER ACTION</b> See paragraph 2 below
Applicant's or agent's file reference	DC-0248	
International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/US04/01382	20 January 2004 (20.01.2004)	21 January 2003 (21.01.2003)
International Patent Classification (IPC) or both national classification and IPC		
IPC(7): A61K 31/519; C07D 487/02; C12Q 1/02 and US Cl.: 435/29; 514/265.1; 544/280		
Applicant		
TRUSTEES OF DARTMOUTH COLLEGE		

1. This opinion contains indications relating to the following items:

- |                                     |              |  |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion   |
| <input type="checkbox"/>            | Box No. II   | Priority   |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention   |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited  |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application   |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application  |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Jeffrey E. Russel Telephone No. (571) 272-1600
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Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/01382

**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- a sequence listing  
 table(s) related to the sequence listing

b. format of material

- in written format  
 in computer readable form

c. time of filing/furnishing

- contained in international application as filed.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority for the purposes of search.

3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US04/01382

**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims <u>3-7</u> _____ YES
	Claims <u>1 and 2</u> _____ NO
Inventive step (IS)	Claims <u>3-7</u> _____ YES
	Claims <u>1 and 2</u> _____ NO
Industrial applicability (IA)	Claims <u>1-7</u> _____ YES
	Claims <u>NONE</u> _____ NO

**2. Citations and explanations:**

Claims 1 and 2 lack novelty under PCT Article 33(2) as being anticipated by Gabry et al. Gabry et al teach in vivo administration of antalarmin in a pharmaceutically acceptable vehicle comprising cremophor, ethanol, and saline. See, e.g., page 475, column 2, second full paragraph. Note that an intended use limitation such as "for increasing cytotoxic T-cell lytic activity" and "for treatment of human ovarian cancer" does not impart novelty or non-obviousness to product claims where the product is otherwise taught by the prior art.

Claims 3-7 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest measuring the level of cytotoxic T-cell lytic activity in cells or tissues which have been contacted with antalarmin, and do not teach or fairly suggest administering antalarmin to tumor-bearing animals, including patients with ovarian cancer. The prior art of record does not teach or suggest that antalarmin has any effect on cytotoxic T-cell lytic activity, on cancer in general, or on ovarian cancer specifically. While Pfizer, Inc. indicates that CRF antagonists have anticancer activity in general (see, e.g., claim 11), there is no teaching or suggestion that antalarmin specifically will act by increasing cytotoxic T-cell lytic activity or anti-tumor activity.

Claims 1-7 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry. The claimed invention would have been expected to have industrial applicability in the therapeutic treatment of tumors.